COLLEGE of AMERICAN PATHOLOGISTS

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The College of American Pathologists (CAP) appreciates the opportunity to comment on the *2017 Interoperability Standards Advisory*. As the leading organization with 18,000 board-certified pathologists, the College of American Pathologists (CAP) serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

COMMENTS
We provide our comments to the sections of the Standards Advisory.

In response to **Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specification, I-I: Lab tests**, we acknowledge the complexity of LOINC and the on-going efforts to improve it for daily use. While LOINC may have the potential to enhance interoperability, we are concerned that reliance solely on LOINC in its present form does not achieve expectations for interoperability within and across health care institutions.

Many laboratories do not have sufficient expertise or resources to assign and maintain LOINC codes. Today the assignment of only a small subset of LOINC codes occurs at the local laboratory level in a variable manner and by individuals with varying backgrounds and expertise. We recommend that to avoid the challenges with LOINC code assignment variability, ONC work with the FDA to request that manufacturers of instruments and lab test kits assign standardized LOINC test and device identification codes and make these codes available to their customers.

Representatives from the CAP participate in the ONC Laboratory TIGER team. This team has identified many issues such as LOINC long name incompatibility with present day information systems. The character length of the LOINC Long Common Name has been identified as a compatibility issue with some LIS and EHR systems, as some systems may truncate the Long Common Name as it is simply too long for them to accommodate. Currently, the character limit for the LOINC Long Common Name is 255, while the limit for the LOINC Short Name is 40. CLIAC previously discussed the long names as not being patient or provider friendly. These two issues of length and "friendliness" resulted in the creation of an ONC project in a TIGER team assigned with the task of creating new naming rules and conventions for LOINC. This team has identified new length limits for the long and short LOINC names as 36 and 12 respectively. However, we understand that Regenstrief Institute does not accept these new LOINC short names.

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In addition, LOINC was designed as a non-hierarchical "flat list" of codes, some of which are generic and correspond to multiple more specific LOINC codes; consequently, each receiving system in need of grouping similar specific LOINC codes into a more general group are left to reinvent the groupings independently each time new LOINC codes are released unless they are pre-specified in an up-to-date multiaxial list. Otherwise, this creates inconsistent groupings across different organizations and therefore has the potential to adversely impact patient care.

We present two “real-world” categories of challenges in using of LOINC:

1. Commonly ordered but hard to code tests: For example, there are 103 laboratory terms for Hepatitis C Virus in LOINC. This list can be narrowed down by selecting the specimen used for the test - in this case we can select serum tests, which results in 64 matching records. This is still too large of a list in which to find the correct LOINC code. Further information must be identified by the coder and used to limit the search such as: is this testing for the presence of antigens or antibodies, and if so-which ones specifically? Does this test detect RNA? Is this a screening test or a quantitative test? What is the specific test methodology used in the testing, such as immunoblot, immunoassay, target amplification? Which does a coder choose?

2. High-throughput genomic sequence analysis: This has many challenges. For many genes, there is a code for the presence of a mutation in a gene and a different code for the test being performed on that same gene. Which does a coder choose? If coding of an actual test result is intended, then this presents challenges to information systems when the result is embedded in a free-text interpretation, as they commonly are. It is not clear whether the word “mutation” is intended to represent a pathogenic variant, as it does in the molecular community, or whether it is intended to represent any variant, for which the word is commonly used. For some genes such as BRAF, specific variants such as the presence of the V600E are specifically coded. However, specific codes for many other clinically significant variants are missing in the existing release. The specific molecular genetics method is not described for many molecular LOINC codes, and this has the potential to cause tests performed by non-comparable methods to be mapped to the same code. Specimen types for many genetic LOINC codes are limited or ambiguously categorized. Finally, the scalability of LOINC for molecular test results in its current format is of serious concern. Even if only “variant present” is recorded for each entire human gene with an unspecified specimen type, then at least 19,000 additional LOINC codes would be required. LOINC will require far greater (ongoing) expansion if testing for specific clinically significant variants are to be represented.

We also recommend that Regenstrief Institute clarifies whether it intends to encode the test performed or the result of the test and to what level of granularity it should occur. A sound, scalable mechanism for coding each possible genomic variant for primary and secondary uses is a critical need that requires further study and likely will require a paradigm outside the scope of an existing standard. Formation of a working group to address this issue may be the best next step. The CAP welcomes the opportunity to collaborate on this matter.

We also recommend that alternatives to LOINC as an interoperability mechanism be explored. Until other options are identified or there are changes within LOINC for laboratory orders, we recommend that ONC’s aLOINC Order Code S&I Framework Final Report be widely distributed. This initiative, which was developed with the assistance of

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CAP members, put together a proposed list of 1532 orderable tests including single analyte tests and test panels. This subset could be utilized to help standardize HL7 interfaces between an EHR and the multiple Laboratory Information Systems to which it is connected. We recommend that ONC conduct further field testing (e.g., intra- and inter- coder variability) of LOINC to fully understand its capabilities and limitations and to determine the extent and correctness of use across enterprises.

In response to **Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specification, I-K: Numerical References and Values**, we support the use of standardized units of measure to help promote interoperability and to reduce errors related to translation of units of measure from one system to another. While we generally support the use of the Unified Code for Units of Measure (UCUM), there are important problems which need to be solved within the UCUM standard before the CAP can recommend it for general use. We are pleased that our 2016 comments have been incorporated into the limitations, dependencies, and preconditions for consideration section.

We recommend that the FDA, CDC and NLM work with UCUM, laboratory professionals and other organizations to resolve the noted limitations, dependencies, and preconditions so that UCUM may be implemented as the official standard for units of measure in the United States.

In response to **II-K: Laboratory, Interoperability Need: Receive electronic laboratory test results,** the CAP encourages the use of the HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 – DSTU Release 2 – US Realm, September 2015. In addition, we encourage the continued development of the S&I Structured Data Capture initiative as a possible adjunct for more complex interoperability needs.

In response to **II-K: Laboratory, Interoperability Need: Ordering Labs for a Patient,** the CAP encourages the continued development of the HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 DSTU Release 2 - US Realm (LOI). In addition, we encourage inclusion of the emerging draft IHE LCC (Laboratory Clinical Communication) profile to provide for a robust mechanism of communication between the ordering provider and the laboratory and to serve as an interoperability framework for laboratory driven clinical decision support.

In response to **II-O: Public Health Reporting, Interoperability Need: Reporting Cancer Cases to Public Health Agencies**, the CAP produces templates for capturing discrete standardized data across a wide array of cancer types and enabling standardized reporting in the United States. Leveraging the many discrete data elements requires robust infrastructure. We applaud ONC listing S&I Structured Data Capture initiative, including FHIR, as Emerging Implementation Specifications due to known limitations of the CDA for structuring cancer data.

CONCLUSION

The CAP appreciates the opportunity to comment on this draft version of the 2017 Standards Advisory. As a leading laboratory organization, we look forward to continued updates from ONC on the Standards Advisory to not only address pathologists' concerns but also to advance interoperable EHRs to improve care for our patients. Should you have any questions on our comments, please contact Mary Kennedy,

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